



## UNITED STATES DEPARTMENT OF COMMERCE

**Patent and Trademark Offic** 

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Washington, D.C. 20231

APPLICATION NO: FIRST NAMED INVENTOR ATTORNEY DOCKET NO. **FILING DATE** 03/260.536 06/16/94 LURENCE 57704 HM21/0526 **EXAMINER** NIXON & VANDERHYE P.C. SCHEINER, L 1100 NORTH GLEBE ROAD 8TH FLOOR PAPER NUMBER **ART UNIT** ARLINGTON VA 22201-4714 1648 05/26/98 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trad marks** 

|   | Application No.         | Applicant/o)                                   |
|---|-------------------------|--|
| Office Action Summary   | Application No.         | Applicant(s)                                   |
|   | Examiner                | Group Art Unit                                 |
|   |                         | 1648   |
| —The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—  |                         |  |
| Period for Response   |                         |  |
| A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  |                         |  |
| <ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.</li> <li>If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> </ul>  |                         |  |
| Status  |                         |  |
| Responsive to communication(s) filed on 189   | }                       |  |
| ☐ This action is FINAL.   |                         |  |
| □ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 1 1; 453 O.G. 213.  |                         |  |
| Disp sition of Claims   |                         |  |
| Claim(s) 148 - 307  |                         | is/are pending in the application.             |
| Of the above claim(s) 144 - 163, 166, 169-176   | 9 178-307               | is/are withdrawn from consideration.           |
| □ Claim(s)  |                         |  |
| Claim(s) 41-143, 64, 165, 167, 168 & 177  |                         | is/are rejected.                               |
| □ Claim(s)  |                         |  |
| □ Claim(s)  |                         | -  |
| Application Papers  |                         | requirement.                                   |
| ☐ See the attached Notice of Draftsperson's Patent Drawing  | Review PTO-948          |  |
| ☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.  |                         |  |
| ☐ The drawing(s) filed on is/are objected to by the Examiner.   |                         |  |
| ☐ The specification is objected to by the Examiner.   |                         |  |
| ☐ The oath or declaration is objected to by the Examiner.   |                         |  |
| Pri rity under 35 U.S.C. § 119 (a)-(d)  |                         |  |
| <ul> <li>□ Acknowledgment is made of a claim for foreign priority under line of the CERTIFIED copies of the line of the l</li></ul> | e priority documents ha | ave been                                       |
| *Certified copies not received:   | ·                       | ,  |
| Attachm nt(s)   |                         | ,  |
| • •   | ۵) ا                    | ntantiau Summan, DTO 412                       |
| ☐ Information Disclosure Statement(s), PTO-1449, Paper No( ☐ Notice of References Cited, PTO-892  |                         | Notice of Informal Patent Application, PTO-152 |
| ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948   |                         | Other  |
|   |                         |  |
| Offic Acti n Summary  |                         |  |

Serial Number: 08/260,536 Page 2

Art Unit: 1648

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Newly presented claims 141-307 are pending. Again, claims 144-163, 166, 169-176 and 178-307 are directed to an invention that is independent from the invention originally claimed. Therefore, claims 144-163, 166, 169-176 and 178-307 are withdrawn by the examiner based on constructive election by original presentation. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03. Please also see Paper No. 22 wherein then newly submitted claims 22, 25, 37, 39-42, 44-47, 50-63, 65, 66, 68, 70-105, 109, 110, 112-116, 118, 119, 121-124, 126, 127, 129-132, and 135-139 were withdrawn since they were directed to an invention that was independent or distinct from the invention originally claimed. Instant claims 144-163, 166, 169-176 and 178-307 correspond to the previously withdrawn claims. Applicants are again reminded that 37 CFR 1.129(a) merely sets forth that the finality of the previous Office action is withdrawn, and not that claims drawn to a new invention may be presented for examination on the merits. Accordingly, claims 141-143, 164, 165, 167, 168, and 177 will be examined on the merits.

Applicants' comments set forth in Paper no. 30 regarding claims withdrawn from consideration by the examiner have been considered but are not persuasive. Essentially, applicants argue that the original claims are comparable to various aspects of new claims 141-163. The examiner contends that the scope of the withdrawn claims differs from the claims prior

Serial Number: 08/260,536 Page 3

Art Unit: 1648

to the filing of the amendment under 37 CFR 1.129(a). Moreover, limitations not previously envisaged have been clearly set forth. Again, applicants are reminded that the finality of the last Office action is removed only under the rule. That is, the scope of the claimed subject matter should not be changed by an amendment filed under the rule.

Claims 141-143, 164, 165, 167, 168, and 177 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment with NDV 73-T, does not reasonably provide enablement for any NDV strain, or any mesogenic NDV strain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. That is, the specification teaches only the use of NDV 73-T strain which is not sufficiently enabling for all NDV strains, or any mesogenic NDVs. Also systemic administration has not been taught in the specification (claims 164-168). Again, the specification is not enabled broadly for the recitation of "mesogenic", nor is the term set forth in the original disclosure. Moreover, the use of any NDV strain has not been taught. It appears that applicants have only disclosed one example of a particular species belonging to the genus mesogenic. Claims must be commensurate in scope with the specification and one example is not enabling for the use of the class or genus of NDVs. In ex parte Jackson, 217 USPQ 805, even a "description of several newly discovered strains of bacteria having one particularly desirable metabolic property in terms of conventionally measured culture characteristics and number of metabolic and physiological properties does not enable one of ordinary skill in the relevant art to independently discover additional strains having same specific, desirable metabolic property". Thus, the degree of experimentation involved in locating new NDVs which would function in the claimed methods apart from deposited cultures is undue in light of enablement requirement of 35 USC 112. The results achieved in instant examples are

not predictive of the effect of any mesogenic NDV on cancers as claimed. Furthermore, examples have not been set forth which would support enablement of claims drawn to administration of any "mesogenic Newcastle disease viruses" to mammals.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 141-143, 164, 165, 167, 168, and 177 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lorence et al. (1988).

Claims 141-143, 164, 165, 167, 168, and 177 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Reichard et al. (1992).

Claims 141-143, 164, 165, 167, 168, and 177 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Reichard et al. (1992).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number:

Serial Number: 08/260,536

Art Unit: 1648

(703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

Laurie Scheiner/LAS May 19, 1998

> LAURIE SCHEINER PRIMARY EXAMINER

Page 5